EXHIBIT N

Suture erosion rates and long-term surgical outcomes in patients undergoing sacrospinous ligament suspension with braided polyester suture

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OBJECTIVE: The objective of the study was to describe suture erosion rates and long-term surgical outcomes in patients undergoing sacrospinous ligament suspension (SSLS) using braided polyester suture.

STUDY DESIGN: This was a retrospective cohort study of patients undergoing SSLS for vaginal prolapse between 1999 and 2005. Outcomes included rate and timing of suture erosion and related symptoms, additional treatment, and long-term success rates.

RESULTS: Sixty-four of 92 subjects had SSLS with braided polyester suture and had an average follow-up of 26.5 months. Suture-related complications occurred in 36% of patients. Mean time to presentation was 18.9 months. Vaginal bleeding occurred in 74%, and suture removal was required in 70% of patients with symptoms. Recurrent prolapse developed in 27% of patients, but additional therapy was required in only 6%.

CONCLUSION: Permanent braided polyester sutures are associated with a high rate of suture-related complications over the long term and frequently require additional intervention to resolve associated symptoms.

Key words: permanent suture, sacrospinous ligament suspension, vaginal erosion, vaginal surgery, vaginal vault prolapse

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Prolapse of the vaginal vault subsequent to hysterectomy remains both a common clinical problem and a significant surgical challenge. A variety of surgical techniques have been described to address this problem. Traditionally correction of vaginal vault prolapse has been approached either abdominally, with fixation of the vagina to the sacrum via a segment of mesh, or vaginally, using sutures to either 1 or both of the sacrospinous ligaments.

Sacrospinous ligament suspension (SSLS) is a well-established technique for the treatment of vaginal vault prolapse and advanced uterovaginal prolapse. The procedure was first popularized in the United States by Nichols.[1] Modifications have been described by Morley and colleagues[2,3] as well as others[4,5] In general, published success rates have been high.[6-8]

The use of permanent suture has been widely advocated in both the repair of abdominal wall hernias and reconstructive vaginal surgery, including SSLS. The rationale for the use of permanent suture is hopefully to provide a durable repair with a lower rate of recurrence than absorbable suture. Braided polyester sutures are commonly used in reconstructive vaginal surgery because of the combination of excellent handling properties and increased tensile strength over monofilament sutures of similar diameter. However, few have reported on the complications of using permanent suture. The aim of the present study was to describe the rate of suture erosion in a series of women undergoing sacrospinous ligament suspension with permanent braided suture by a single surgeon over an extended follow-up period.

Materials and Methods

Institutional review board waiver was obtained for this retrospective review of office charts by the authors' primary institution. A surgical database maintained prospectively by the senior author (M.R.T.) was reviewed to identify cases. The charts of each patient were manually reviewed by 1 of the authors and the data abstracted. Data collected included demographics, preoperative examination, concomitant surgical procedures, and data from the postoperative visits.

Preoperative assessment of prolapse stage was performed according to the Baden Walker halfway system, early in the study, or the Pelvic Organ Prolapse Quantification system.[9] Patient age and surgical history, including prior operations for pelvic organ prolapse, were recorded. For each case, concomitant procedures including hysterectomy, anterior and posterior repairs, and pubovaginal slings were recorded. At each postoperative visit, patients were screened for the occurrence of bleeding or pain, and physical examination for the presence of suture erosion, granulation tissue, and recurrent pelvic organ prolapse was recorded. In cases in which su-

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TABLE 1
Summary data

Total number of cases	92
Cases excluded	28
Cases analyzed	64
Mean patient age (y)	66
Mean length of follow-up (mo)	26.5
Patients with prior surgery	50 (78%)
Patients with prior hysterectomy	40 (63%)

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ture erosion or granulation tissue was present, the occurrence of symptoms, such as bleeding, discharge, or pain as well as the need for treatment or surgical intervention was recorded. For patients with prolapse recurrence, clinically significant recurrence or surgical failure was defined as the presence of prolapse beyond the introitus or patient request for subsequent therapy (surgery or pessary). For each case of suture-related complications or surgical failure, the time to presentation was recorded. For patients requiring additional surgery or treatment, the date of treatment and the surgical outcomes were recorded.

The surgical technique used was a modification of the Michigan Four Wall Sacrospinous Suspension technique as described by Morley and colleagues.[2,3] This procedure was modified in that the suspension sutures were placed utilizing a disposable throw-and-catch suturing device (Capio, Boston Scientific Corp, Natick, MA) The Capio needle driver was used to deliver 2 no. 0 polyester sutures (Boston Scientific) through the sacrospinous ligament. A bilateral suspension with 2 sutures through each ligament was performed in the majority of cases. The vaginal apex was initially grasped with an Allis clamp on either side of the apex of the prolapse so that these points would comfortably reach the ipsilateral ligament without excess tension or sagging. If excess vaginal mucosa existed, 2 additional Allis clamps were placed on the anterior and posterior vaginal wall in locations that would eliminate redundant mucosa at the apex. This redundant mucosa was then sharply excised without entering the peritoneal cavity.

Dissection was then carried out in the retroperitoneal plane at each lateral angle of the vagina to reach the sacrospinous ligament-coccygeus muscle complex. The 2 sutures were placed through the sacrospinous ligament side by side beginning 2 cm medial to the ipsilateral ischial spine and then attached to the fibromuscular layer of the vagina (not including the surface epithelium) at the ipsilateral vaginal angle. One arm of the suture was placed along the anterior margin of the incised cuff and the second arm through the posterior edge so that the edges of the vagina would come together and slide up against the ligament when tied.

The vagina was closed transversely with interrupted absorbable sutures. The SSLS sutures were tied last to bring the apex of the vagina up against the sacrospinous ligament on each side. At the conclusion of the suspension, the sutures were cut short, with the knots buried beneath the suture line.

TABLE 2
Concomitant procedures performed in 64 patients with SSLS

Procedure	n	%
Anterior repair	3	4.7
Anterior repair, posterior repair	19	29.7
Anterior repair, posterior repair, TVH	7	10.9
Anterior repair, posterior repairs, TVH, PVS	3	4.7
Anterior repair, posterior repair, PVS	10	15.6
Anterior repair, PVS	4	6.3
Anterior repair, TVH	1	1.6
Posterior repair	11	17.2
Posterior repair, TVH, PVS	1	1.6
Posterior repair, PVS	2	3.1
Total	61	95.3

PVS, pubovaginal sling; *TVH*, transvaginal hysterectomy.

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Results

A review of the surgical database revealed that 92 women underwent SSLS between April 1999 and December 2005. The follow-up period included office visits through June 2007. Initial chart review excluded 28 patients: 16 had incomplete records or follow-up of less than 4 weeks. Twelve additional patients were excluded for the use of suture other than braided polyester for the SSLS. This left a cohort of 64 patients (69% of the total cases) that had SSLS with braided polyester suture, had complete records for review, and had follow-up of longer than 4 weeks for analysis.

The women ranged in age from 47 to 84 years with a mean age of 66 years. A total of 23 patients were older than age 70 years (36%), and 7 patients were older than age 80 years (11%). Table 1 summarizes patient characteristics.

Bilateral SSLS was performed in 53 patients (83%), and a unilateral suspension to the right sacrospinous ligament was performed in the remaining 11 patients. Unilateral suspension was performed when it was felt that insufficient vaginal length existed to allow for a relatively tension free suspension of the apex to both sides. Eight patients (13%) had graft augmentation in either the anterior or posterior compartments. In these 8 patients, the permanent SSLS sutures were used to anchor the grafts at the cephalad margin to the sacrospinous ligament, and delayed absorbable sutures were used to anchor the caudad margin of the graft distally to the endopelvic fascia. Concomitant surgical procedures performed are presented in Table 2.

The mean length of follow-up for all patients was 26.5 months (range 1-72 months), with 78% of patients having greater than 12 months of follow-up and 53% having greater than 24 months of follow-up. The mean length of follow-up for patients with suture-related complications was 33.4 months (range 1.9 to 72 months). The mean length of follow-up for patients with clinical failures was 22 months (range 1.9 to 56.2 months).

TABLE 3
Suture erosion summary data

	n	%
Total suture-related complications (n)	23	36
Mean time to presentation (mo)	18.9	
Range	1.9 to 51.2	
Exposed suture (n)	13	57
Mean time to presentation (mo)	25	
Range	3.3 to 51.2	
Granulation tissue (n)	12	61
Mean time to presentation (mo)	2.3	
Range	1.9 to 42.4	
Vaginal bleeding (n)	17	74
Mean time to presentation (mo)	17.6	
Range	1.9 to 51.2	
Asymptomatic erosion (n)	6	26
Mean time to presentation (mo)	22.8	
Range	3.3 to 49.5	
Suture removal (n)	16	70
Return to operating room (n)	9	56

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Suture-related complications occurred in 36% of patients (23 of 64). Table 3 summarizes data regarding suture erosions. Suture erosion was not observed in any of the patients that underwent graft augmentation. Erosion of the suture through the vaginal epithelium was observed on speculum examination in 57% of these women (13 of 23). The mean time to diagnosis of any suture-related complication (granulation tissue or exposed suture) was 18.9 months (range 1.9 to 51.2 months). Vaginal bleeding was reported in 74% of the patients with suture-related complications (17 of 23), whereas 26% (6 of 23) were asymptomatic at initial presentation. Of the 23 patients with suture-related complications, 70% (16 of 23) required removal of the suture because of bothersome bleeding or discharge. Removal of sutures was required in 25% of all patients in our cohort (16 of 64). Sutures were successfully removed in the office in 7 of 16 women (44%). However, 9 of the 16 women (56%) required a return to the operating room. The overall rate of repeat surgery for suture-related complications in our cohort was 14% (9 of 64).

Recurrent prolapse, with or without symptoms, developed in 17 patients (27%) during the follow-up period. Mean time to recurrence was 15.9 months (range 2.8 to 53 months). The most common site of failure was the anterior compartment (11 cases). The remaining 6 patients had failure of apical support. However, only 6% of the patients in our cohort required subsequent therapy for vaginal prolapse with 3% (2 of 64) undergoing repeat surgery. Recurrent prolapse was asymptomatic or minimally symptomatic in the vast majority of patients. Subsequent treatment included the use of a pessary in 2 patients and repeat surgical repair in the remaining 2 patients (1 patient underwent an abdominal sacral colpopexy, and the other underwent an anterior pelvic floor repair with synthetic mesh, anterior Prolift).

COMMENT

Reconstructive vaginal surgery for pelvic organ prolapse poses significant surgical challenges, and the rates of recurrent prolapse and need to additional surgery are widely acknowledged to be high. The use of permanent suture is widely advocated in the surgical correction of pelvic floor defects. In theory, permanent sutures may improve long-term success and durability, compared with procedures done with absorbable sutures. Braided polyester sutures such as Ethibond (Johnson and Johnson, Somerville, NJ) has been a popular choice among gynecologic surgeons because of their excellent handling properties, ease of tying knots, and increased tensile strength over monofilament sutures of similar diameter. However, few studies have been published regarding long-term suture-related complications. Suture-related complications, such as suture erosion, development of persistent granulation tissue, and associated bothersome symptoms such as bleeding were seen in a high percentage of patients in our series and required additional intervention in the majority of cases (70%). It has been our experience that treatment, other than complete removal of the suture (such as fulguration or simple excision of the granulation tissue) has been universally unsuccessful.

Similar experience with braided suture has been previously reported. Luck et al[10] observed a 31.3% suture erosion/wound dehiscence rate, compared with a 9% rate when braided polyester was used instead of polyglactin 910 for defect-specific posterior colpoperineorrhaphy or anal sphincteroplasty. In this retrospective cohort study, more than 70% of these patients were symptomatic, and 16% of these patients required additional surgical intervention. This is similar to our own findings of suture-related complications in 36% of our patients, with 14% requiring a return to the operating room.

The frequent occurrence of suture-related complications may be explained by several factors that may be unique to the vaginal environment or our specific technique for performing this procedure. First, the vaginal epithelium and underlying fibroconnective tissue are relatively thin structures with an extensive vascular supply. Patients with pelvic

organ prolapse tend to be postmenopausal, with evidence of vaginal atrophy and comparatively thinner vaginal walls. The suspension sutures may also be subject to chronic mechanical abrasion, with valsalva pressures or possibly sexual intercourse. One weakness of our study is that we did not have the power to analyze whether a postmenopausal state or use of estrogen cream would have changed the risk of suture-related complications. In our experience, the use of estrogen cream to treat vaginal bleeding in these situations has decreased but not eliminated symptoms.

Two aspects of the Michigan technique for SSLS may increase the risk of suture erosion. First, this technique typically places the vaginal incision directly over the leading edge of the prolapsed vagina, which is typically the thinnest wall of the prolapsed tissue. Second, the sutures for the suspension are placed directly underneath the line of the incision, which can be considered to be the most likely site for wound separation. Lastly, it is possible that our technique of a bilateral suspension could place increased tension on the corners of the repair, further increasing the risk of suture erosion. Interestingly, suture erosion was present at only 1 of the vaginal angles in the patients who underwent a bilateral suspension.

Another possible contributor to the development of suture-related complications is the development of subclinical infection or perhaps a chronic foreign body reaction to the braided suture material. This theory could be supported by the early presentation of most patients in this study with nonhealing granulation tissue (mean time 2.3 months) and the fact that chronic granulation and inflammation was seen on surgical pathology in each of the specimens sent from the operating room. High rates of erosion with the need to completely excise the offending material have also been recently reported with the use of braided or woven materials used in suburethral tape procedures.[11,12]

Overall, the success of the SSLS in alleviating symptoms associated with pelvic organ prolapse was high in this study, with only 6% of patients requiring additional therapy for vaginal prolapse. However, as is common in reconstructive vaginal surgery, recurrence of prolapse in either an adjacent or same compartment was common and was observed in 27% of patients with a mean time to recurrence of 15.9 months. Others have reported similar results with this technique. Holley et al[13] reported on recurrent pelvic support defects following SSLS in a cohort of 36 patients with a median follow-up of 42 months. In this report, 92% and 8% of patients had evidence of recurrent cystoceles and vault prolapse, respectively. As in our series, the majority of recurrences were judged to be asymptomatic. In contrast, Hefni and El-Toukhy[14] reported on a series of 305 women who underwent SSLS and were followed up for a median of 57 months. In this series, 11% of women developed recurrent prolapse.

In conclusion, the use of braided polyester suture for SSLS using the modified Michigan 4 point suspension was associated with a high rate of suture-related complications. Although most of these patients had evidence of chronic granulomatous response early in the postoperative period, 57% of our patients presented with exposed suture at a mean time of more than 24 months following surgery, highlighting the need for long-term surveillance of patients who undergo reconstructive vaginal surgery with permanent suture materials. Given that the rate of recurrent prolapse was not significantly better than that reported by others, we cannot advocate the use of braided polyester with this technique, and in general, we are more reluctant to use it in other vaginal procedures such as a high uterosacral vault suspension and rectocele repairs as well. Finally, we are uncertain that a bilateral suspension offers any significant advantage to the traditional unilateral suspension, and we have some concern that a bilateral suspension may increase the risk of a subsequent "high cystocele," by stretching the already-weakened fibroconnective vaginal layer between the 2 spines. ■

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